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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/829,040 | 04/09/2001 | Junying Yuan | 00742/057002 | 8382 |

21559 7590 06/13/2003

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BOSTON, MA 02110

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| EXAMINER |
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WANG, SHENGJUN

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| ART-UNIT | PAPER NUMBER |
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1617

DATE MAILED: 06/13/2003

12

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/829,040

Applicant(s)

YUAN ET AL.

Examiner

Shengjun Wang

Art Unit

1617

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 March 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-24 is/are pending in the application.
- 4a) Of the above claim(s) 4,5,9,13,16 and 17 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3,6-8,10-12,14,15 and 18-24 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 5&11.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

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DETAILED ACTION

1. Claims 10 and 16⁻¹⁷ withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, claim 4, 5 and 13 are withdrawn from further consideration as drawn to nonelected species, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 9.

2. Applicant's election with traverse of invention group II, claims 1-9, 11, and Congo red as the species in Paper No. 9 is acknowledged. The traversal is on the ground(s) that claim 12-15 and 18-24 are now dependent claims of elected claims as amended. The arguments and amendments construct rally list the subject matter in invention group III is a subgenus of the subject matter in invention group II. The arguments are persuasive and claims 12-15 and 18-24 are rejoined to the elected invention. Applicants also traverse the restriction and species election on the ground that the search of all claimed invention would post no undue burden. This is not found persuasive because search of one invention, e.g., male infertility, would not required for the search of other invention, e.g., cell death or toxicity. Further, the search is not limited to patent literature. As to the species election, note the instant claims encompass various structurally distinct compounds, a species election for search purpose is proper.

The requirement is still deemed proper and is therefore made FINAL.

The claims have been examined insofar as they're read on the elected invention and species.

Claim Rejections 35 U.S.C. 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 1-3, 6-9, 11, 12, 14, 15 and 18-24 rejected under 35 U.S.C. 103(a) as being unpatentable over Klunk et al. (US 6,417,178), in view of Klunk et al. and Huang et al.

5. Klunk et al ('178) teaches a method of treating various diseases associated with amyloid deposits comprising administering to a subject in need thereof an amyloid binding agents. The diseases including Huntington diseases. The amyloid binding agents includes analogues of Congo red. See, particularly, the claims, especially, claim 18.

6. Klunk et al. does not teach expressly to employ Congo red as the amyloid binding agents. However, Klunk et al. teaches that Congo red and the Congo red analogues employed in '178 are known to be similarly useful as amyloid binding agents for reducing toxicity. See, the abstract. Huang et al. teaches that Congo red binding to the amyloid from Huntington diseases which have expanded polyglutamine segment. See the abstract.

Therefore, it would have been prima facie obvious to a person of ordinary skill in the art, at the time the claimed the invention was made, to employ Congo red for treating a subject with Huntington disease.

A person of ordinary skill in the art would have been motivated to employ Congo red for treating a subject with Huntington disease because Congo red is known to be useful as amyloid binding agent, and particularly for binding to amyloid in Huntington disease. As to claim 3, note

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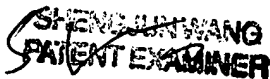
since Congo red is known to effectively binding to amyloid from Huntington disease, one of ordinary skill in the art would have been motivated to employ Congo read for treating Huntington disease or diseases with similar amyloids to the amyloid found in Huntington disease.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shengjun Wang, Ph.D. whose telephone number is (703) 308-4554. The examiner can normally be reached on Monday-Friday from 8:30 to 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan, can be reached on (703) 305-1877. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Patent Examiner

SHENGJUN WANG
PATENT EXAMINER

Shengjun Wang

June 7, 2003